REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1, 4-5, 7 and 17-20 are pending in this application. Claims 4, 5, 7, 17 and 18 are withdrawn from consideration. Claim 1 is amended and claims 2 and 6 have been cancelled. Claims 19-20 are newly added. Claims 1, 17 and 18 are the independent claims.

Applicants respectfully note that the present action does not indicate that the claim to foreign priority under 35 U.S.C. §119 has been acknowledged or that certified copies of all priority documents have been received by the U.S.P.T.O. Applicants respectfully request that the Examiner's next communication include an indication as to the claim to foreign priority under 35 U.S.C. §119 and an acknowledgement of receipt of the certified copies of all priority documents.

Applicants also respectfully note that the present action does not indicate that the drawings have been accepted by the Examiner. Applicants respectfully request that the Examiner's next communication include an indication as to the acceptability of the filed drawings or as to any perceived deficiencies so that the Applicants may have a full and fair opportunity to submit appropriate amendments and/or corrections to the drawings.

New Claims

By the present Amendment, Applicants submit that claims 19-20 have been added. Support for new claims 19-20 can be found in at least in the Specification as originally filed. In particular, support for claims 19-20 can be found at least on page 4, line 21 and page 5, line 2. As such, Applicants submit that no new matter has been added.

Restriction/Species Election

Applicants confirm the election of Group I, claims 1, 2 and 6. In addition, Applicants elect the target-cell substance of interferons in regards to claim 6.

Specification

The specification is amended herewith to correct minor informalities. More specifically, pages 15, 19, 22-23, 26-27, and 31 are amended to correct the citation of the sequence numbers.

The Applicants hereby confirm their willingness to cooperate with the Examiner in the identification and correction of further minor errors within the specification. The Applicants respectfully submit, however, that they are not presently aware of any such errors that would require correction.

Rejections under 35 U.S.C. § 112

Claims 1, 2 and 6 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 2 and 6 have been cancelled, so the rejection with regards to claims 2 and 6 is now moot.

In particular, the Examiner asserts that the claims cover a broad range of viral particles containing "a disease-treating target-cell-substance". The Examiner asserts that since there are allegedly no structural limitations to the particle-forming protein and target-cell-substance in claim 1, the scope of the claims encompass any particle-forming proteins containing any substances that can target cells or treat a disease.

Applicants submit that the amendments to claim 1 should provide structural limitations to the particle-forming protein and target-cell-substance disclosed in independent claim 1. Applicants also submit that independent claim 1 is supported by examples described in the specification, but in particular, page 4, lines 21-23.

Accordingly, Applicants submit that the specification is enabling and respectfully request that the rejection of claims 1, 2 and 6 under 35 U.S.C. §112, first paragraph, be withdrawn.

Example Embodiment of the Present Application

A non-limiting example embodiment of a pharmaceutical compound is explained on page 4, lines 21-23 of the present specification. A feature of example embodiments is the use of a protein capable of recognizing specific cells (e.g., hepatitis B virus surface-antigen protein). That use enables a target-cell substance (interferon, hepatocyte growth factor, or interleukin) to be transported to a specific targeted site (e.g., hepatocytes). The pharmaceutical compound contains a hepatitis virus surface-antigen protein capable of recognizing a hepatocyte and contains any one of an interferon, hepatocyte growth factor, or interleukin as a target cell substance.

Furthermore, hepatitis B virus surface-antigen protein is capable of recognizing hepatocytes and has strong infectivity specific to hepatocytes. That is, the protein is capable of recognizing and and binding with hepatocytes, and delivering the target-cell substance in particles into the hepatocytes. Therefore, the pharmaceutical compound transfers drugs efficiently to hepatocytes (target site). The compound may be administered in a relatively small amount and still be effective in liver disease treatment.

Rejections under 35 U.S.C. § 102

Valenzuela

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Valenzuela (1985,Biotechnology Vol. 3, pp 323-326, cited in the IDS). Applicants respectfully traverse this rejection for the reasons detailed below.

Claim 2 has been cancelled, so the rejection with regards to claim 2 is now moot.

The Examiner asserts that Valenzuela discloses a hybrid particle that contains both HBsAg and herpes simplex virus (HSV) surface antigen gD and that herpes simplex virus (HSV) surface antigen gD is equivalent to the disease-treating target-cell substance of independent claim 1. Applicants respectfully disagree.

Valenzuela neither discloses nor suggests the use of a hepatitis virus surface-antigen protein as a protein capable of recognizing hepatocytes for the purpose of transporting a target-cell substance to the hepatocytes as disclosed in amended, independent claim 1.

The Applicants, therefore, respectfully request that the rejection to Claims 1 and 2 under 35 U.S.C. § 102(b) be withdrawn.

Furthermore, newly-added claims 19-20 are also allowable over Valenzuela, at least by virtue of their dependency on independent claim 1.

Kingsman

Claims 1 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kingsman (US 5,008,373). Applicants respectfully traverse this rejection for the reasons detailed below.

Claim 6 has been cancelled, so the rejection with regards to claim 6 is now moot.

Kingsman discloses fusion proteins, for example, a fusion protein using a yeast TYA gene as the first amino acid sequence. Kingsman also gives a more specific example of a fusion protein which is the use of interferon (IFN) as the second amino acid sequence.

However, the yeast TYA gene given as the first amino acid sequence differs from the hepatitis B virus surface-antigen protein of example embodiments. In addition, Kingsman does not disclose that the TYA gene is capable of recognizing specific cells or tissues.

Therefore, Kingsman neither discloses nor suggests the hepatitis B virus surface-antigen protein which is a protein capable of recognizing hepatocytes as disclosed in independent claim 1.

The Applicants, therefore, respectfully request that the rejection to Claims 1 and 6 under 35 U.S.C. § 102(b) be withdrawn.

Furthermore, newly-added claims 19-20 are also allowable over Kingsman, at least by virtue of their dependency on independent claim 1.

Double Patenting

Claims 1 and 2 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 24, 25, 28 and 30-33 of copending application of 10/220,125, Claims 1-7 and 9 of co-pending application 10/529,749 and Claims 1 and 2 of co-pending application 10/509,248.

Claim 2 has been cancelled, so the rejection with regards to claim 2 is now moot.

The amendments to independent claim 1 include the features of dependent claim 6 for which no double patenting issue is raised. The Applicants, therefore, respectfully request that the rejection to Claims 1 and 2 on the ground of nonstatutory obviousness-type double patenting be withdrawn.

Furthermore, Applicants cannot remedy this rejection at this time and request that this rejection be held in abeyance. This is because none of the co-pending applications has matured into a patent. Should all outstanding issues in the present application be resolved save for the double-patenting rejection, and should none of the co-pending applications have by such time matured into a patent, then the Examiner should allow the instant application and thus any double patenting rejection should attach to the above-noted co-pending applications.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By _____

Donald J. Daley, Reg. No. 34,313
P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

DJD/EGH:ald